U. S. DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENT, SAFETY AND HEALTH

Office of Worker Health and Safety (EH-5)

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CHRONIC BERYLLIUM DISEASE PREVENTION PROGRAM

Notice of Proposed Rulemaking (NOPR)

Docket Number EH-RM-98-BRYLM

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PUBLIC HEARING

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Thursday, February 11, 1999

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The Meeting took place at the U.S. Department of Energy, 1000 Independence Avenue SW, Washington, D.C. at 9:00 a.m., David Michaels, Presiding Official, presiding.

PANEL:

DAVID MICHAELS, Presiding Official
JOSEPH FITZGERALD, JR.
PAUL J. SELIGMAN
C. RICK JONES
JACQUELINE ROGERS
EDWARD LEDUC

SPEAKERS:

GARY BATYKEFER
BARBARA HARGIS
MARC KOLANZ

RAFAEL PONCE
ILISE FEITSHENS
RICHARD MILLER

A-G-E-N-D-A

P-R-O-C-E-E-D-I-N-G-S

(9:00 a.m.)

PRESIDING OFFICIAL MICHAELS: Good Morning and welcome.

I am Dr. David Michaels, Assistant Secretary for Environment, Safety and Health.

On behalf of the Department of Energy, I would like to thank you for taking the time to participate in this public hearing concerning the proposed Chronic Beryllium Disease Prevention Program particularly those of you who have come from some distance.

The purpose of this hearing is to receive oral testimony from the public on DOE's Notice of Proposed Rulemaking, which I will call NOPR. I know non one likes to call it that, but I will.

Your comments are not only appreciated, they are essential to the process.

The publishing of the NOPR that is the subject of today's public hearing, has been preceded by two years of information gathering and data analysis by the Department.

In 1996, the Department surveyed its contractors to characterize the extent of beryllium usage, the types of tasks involving beryllium usage, the controls in place for each task, and the estimated exposure levels associated with each task.

To supplement the data obtained from the 1996 survey, the Department published a Federal Register notice on December 30, 1996, requesting scientific data, information, and views relevant to a DOE beryllium health standard.

The survey and Federal Register notice were followed by two Beryllium Public Forums, held in Albuquerque, New Mexico, and Oak Ridge, Tennessee, January 1997.

While the Department moved forward with its rulemaking process, an Interim Chronic Beryllium Disease Prevention Program was issued on July 15, 1997, as DOE Notice 440.1 to direct immediate action for the protection of workers while rulemaking efforts continued.

The Interim Notice established a CBDPP that enhanced and supplemented worker protection

programs already required by current worker safety and health orders with provisions that are designed to manage and control beryllium exposure hazards in the DOE workplace.

Because of the complexity and significance of issues regarding the development of a DOE health standard for beryllium, a Beryllium Rule Advisory Committee (BRAC) was established in June 1997 to advise the Department on issues pertinent to the proposed rulemaking activity.

DOE also used the BRAC recommendations and the lessons learned in the implementation of DOE Notice 440.1 to develop the NOPR.

The objectives of the NOPR are to: 1) minimize the number of workers exposed to beryllium; 2) minimize the levels of beryllium exposure and the potential for beryllium exposure; 3) establish medical surveillance protocols to ensure early detection of CBD; and 4) assist affected workers who are dealing with beryllium health effects.

In addition, the Department intends to collect and analyze exposure and health data as part

of its ongoing beryllium-related research efforts to ensure the protection of workers' health.

DOE will consider amendments to its regulations as additional information and feedback are collected.

If you have not already read the Federal Register Notice from December 3rd of 1998, I urge you to do so. Copies are available at the registration desk.

The comments received here today, and those submitted during the written comment period, which ends March 9th, will assist the department in the rulemaking process.

All written comments must be received by this date to ensure consideration by DOE. The address for sending in comments is, Jacquelyn D. Rogers, U.S. Department of Energy, Office of Environment Safety and Health, EH-51, docket number EH-RM-98-BRYLM, 1000 Independence Avenue Southwest, Washington, D.C., 20585.

As the presiding official for this Hearing, I would like to set forth the guidelines for

conducting the Hearing, and provide other pertinent information.

In approximately 14 days a transcript of this Hearing will be available for inspection and copying at the Department of Energy's Freedom of Information reading room, here in Washington, D.C., as well as at the DOE Oakridge and Rocky Flats public reading rooms.

The addresses are specified in the Federal Register Notice, and they are also available at the registration desk. The transcript will also be placed on the Office of Environment Safety and Health's Chronic Beryllium Disease Prevention Programs internet webpage, which can be accessed at

http:\\tis.ek.doe.gov\be\.

In addition, anyone wishing to purchase a copy of the transcript may make their own arrangements with the transcriber reporter.

This will not be an evidentiary or judicial type of Hearing. It will be conducted in accordance with section 553 of the Administrative Procedure Act, 5 U.S>C. section 553, and section 501

of the DOE Organization Act, 42, U.S.C. section 7191.

To provide the Department with as much pertinent information and as many views as can reasonably be obtained, and to enable interested persons to express their views the Hearing will be conducted in accordance with the following procedures.

Speakers will be called to testify in the order indicated on the agenda. Speakers have been allotted ten minutes for their verbal statements. Anyone may make an unscheduled oral statement after all scheduled speakers have delivered their statements. To do so, please submit your name to the registration desk before the conclusion of the last scheduled speaker, and at the conclusion of all presentations, scheduled and unscheduled.

Speakers will be given the opportunity to make a rebuttal, or clarify a statement. To do so, please submit your name to the registration desk.

Questions of the speakers will be asked only by members of the DOE panel conducting the Hearing. As I explained, the purpose of this Hearing is to receive testimony from the public on DOE's

notice of proposed rulemaking.

It is not the purpose of this Hearing to discuss individual lawsuits that have been filed in Court, or claims that have been filed under the Federal Tort Claims Act.

This panel will, therefore, not discuss litigation or claims. Instead, I urge all speakers to provide this panel with comments, opinions, and pertinent information about the proposed Rule.

As mentioned earlier, the close of the comment period is March 9th, 1999. All written comments received will be available for public inspection at the DOE Freedom of Information reading room in Washington, D.C., telephone number 202-596-3142.

Ten copies of the comments are requested. If you have any questions concerning the submission of written comments, please see Andy Kasarsky at the registration desk. She can also be reached at 202-586-3012.

Any person submitting information which he or she believes to be confidential and exempt by law

from public disclosure should submit to the Washington, D.C. written comments address a total of four copies, one complete copy with the confidential material included, and three copies without the confidential information.

In accordance with the procedures established at 10CFR1004.11, the Department of Energy shall make its own determination as to whether or not the information shall be exempt from public disclosure.

In keeping with the regulations of this facility, there will be no smoking in this room.

We appreciate the time and effort you have taken in preparing your statements, and are pleased to receive your comments and opinions.

I would like to now introduce the other members of this panel. Joining me today is Joseph Fitzgerald, Jr., Deputy Assistant Secretary for Worker Health and Safety, also known as EH-5; Dr. Paul Seligman, Deputy Assistant Secretary for Health Studies, EH-6; C. Rick Jones, Director of the Office of Worker Programs and Hazards Management, EH-52,

within the Office of Worker Health and Safety; Jacqueline Rogers, Industrial Hygienist, Office of Occupational Safety and Health Policy, EH-51, and Edward LeDuc, Attorney, Office of the General Counsel.

This introduction has been lengthy, but I hope useful. Now it is time to move on to the reason why we are all here, to listen to your comments on the NOPR.

I would like to call our first speaker on the agenda. For the record, I ask that each speaker please state his or her name, and whom you represent before making your statement.

Our first speaker today is Gary Batykefer, if you would come forward, please. And, again, please state your name and who you represent, for the record.

MR. BATYKEFER: Good morning. My name is Gary Batykefer, I represent the Sheet Metal Workers International Association. It is certainly a pleasure to be here today and address the panel.

The Sheet Metal Workers International Association, through their Health and Safety Department , have a number of issues of concern

regarding the Department of Energy proposed regulations establishing a chronic beryllium disease prevention program.

Members of the Sheet Metal Workers International Association are routinely employed on Department of Energy sites in a varied number of roles. Many are employed in maintenance repair and operations, or work for an outside contractor in a subcontracting assignment.

Therefore, it is imperative that the same level of protection be afforded all sheet metal workers working in the maintenance of the facility as well as those working for subcontractors.

Department of Energy contractors are required under DOE order 440.1A to have general worker protection programs.

The Sheet Metal Occupational Health Institute Trust has learned through our involvement with asbestos, that specific hazardous materials training is critical to the safety of our members.

As in the case of asbestos exposure, sheet metal workers exposed to beryllium dust or fumes may

develop chronic beryllium disease (CBD) in a short period of time or many years after exposure to beryllium.

With that in mind our position to have all personnel on DOE sites attend an initial 40 hour HAZWOPER certification course recognized by the Department of Labor, and Department of Energy as a requirement to work on a site, could dramatically reduce CBD exposures.

A requirement to attend an annual refresher update course would also be desirable and required in our proposal. Specific attention would be given to address beryllium exposures as well as chronic beryllium disease within the curriculum of the 40-hour initial and the 8-hour refresher courses.

It is the intention of the Sheet Metal Workers International Association to reduce exposure to the sheet metal worker as well as those working in multi-craft zones and family members through education and awareness training.

This program would address proposed section 850.2(a)(1) and 850.2(a)(2).

Due to the nature of multi-craft participation on DOE sites it is the contention of the Sheet Metal Workers International Association that each craft be in charge of training the workforce in hazardous materials awareness.

Craft specific input must be considered in the development of the training programs and should be germane to all DOE sites.

Pertaining to proposed section 850.10(a)(2) requiring a single written chronic beryllium disease prevention program to encompass all related activities on the site, it is our contention that specific craft guidelines be implemented on all DOE sites as a national compliance issue, as contractors, doing specified trade related work, change from time to time and in some cases job to job.

Proposed section 850.24(c), exposure monitoring, requires that monitoring be done by individuals with sufficient knowledge in industrial hygiene on a quarterly basis.

It is the opinion of the SMWIA, that this is inconsistent with the low end of the latency period

for chronic beryllium disease, which is only a few months.

Therefore it is our opinion that monthly monitoring be done while working in a constant area and immediately when initial work is begun in a new work area.

Proposed section 850.29 stipulates that workers must exchange their personal clothing for protective clothing before beginning work in regulated areas.

This should be consistent with the provisions set for by OSHA for asbestos removal as any residue could be transmitted through laundering of work clothes to family members.

Proposed section 850.33(h)(4) regarding medical evaluations and procedures. The Sheet Metal Occupational Health Institute Trusts would require that all records pertaining to individual medical examinations, medical surveillance, and records demonstrating the effectiveness of related programs be maintained and forwarded to the Local Sheet Metal Workers local Union as well as the Sheet Metal Workers

International Association.

The reason for this request is that we have a relationship established with Hunter College and have an established data base for tracking worker's health.

This information is used to determine how our members have been affected by exposure to asbestos through this database.

The results of any testing related to beryllium exposure could be easily folded into this established system as stipulated in 850.39(a) of this proposal.

In conclusion, the Sheet Metal Workers International Association reserves the right to continue to review the Beryllium Rule and forward additional comments regarding this proposal in the proper time frame.

If you have any questions regarding this you can certainly get in touch with me at 703-739-7130.

I thank you very much for your time.

PRESIDING OFFICIAL MICHAELS: Thank you

very much. Let me ask the panel if you have any questions of clarification for this speaker?

(No response.)

PRESIDING OFFICIAL MICHAELS: Thank you very much. Our next speaker, Barbara Hargis.

MS. HARGIS: Good morning. I am Barbara Hargis, I'm Group Leader of the Industrial Hygiene and Safety Group at Los Alamos National Laboratory.

I am here today representing the views of the University of California Office of the President and its three laboratories, Los Alamos National Lab, Lawrence Livermore National Lab, and the Lawrence Berkeley National Laboratory.

With me here today are Kenny Rhodes of the University of California Office of the President, Jim Jackson from Livermore, and Dina Suselma from Los Alamos.

We welcome the opportunity to appear here today to provide input as DOE continues to gather comments on the proposed rule Chronic Beryllium Disease Prevention Program.

On July 15, DOE issued Notice 440.1

"Interim Chronic Beryllium Disease Prevention Program" prior to which the UC, as well as other organizations submitted extensive comments.

DOE continued to gather information on the implementation of beryllium programs across the Complex and sponsored several conferences to facilitate the sharing of information.

DOE should be commended for incorporating many suggested changes into the rule that is proposed today.

The University of California is firmly committed to the premise of protection of employees and we wholeheartedly support DOE's efforts to promulgate a performance based approach to protection of workers from beryllium.

We also believe that DOE should continue to invest in the improvement of existing technologies and in the development of new technologies which could improve control and measurement techniques for beryllium.

There are several areas of the proposed rule and request for information that UC of California

would like to address. They are focused in the technical areas including contamination level and percent exceedance; medical areas including surveillance, removal, and privacy issues; and lastly administrative issues.

I will begin with a discussion of the technical issues.

DOE has concluded that existing scientific data does not provide an adequate basis for the establishment of a new exposure limit.

In the preamble to this rule, DOE has relied almost entirely on exposure data from Rocky Flats and the Oak Ridge Y-12 plant.

Much of this data is based on area samples, which typically underestimate personal exposures. It is recommended that DOE continue to gather data on beryllium exposures, disease, and sensitivity experience from all available sources.

We would highly encourage DOE to include an analysis of the monitoring data from the Atomic Weapons Establishment (AWE), at Cardiff, Wales in the preamble.

The AWE conducted beryllium operations beginning in the early 1960's, and collected over 367,000 area and 217,000 breathing zone samples. This data might help to better define a dose-response relationship for beryllium exposure.

Second item, it is stated in Section 850.30(a) Housekeeping, where beryllium is present at DOE facilities, DOE contractors shall conduct routine surface sampling to determine housekeeping conditions. Surfaces contaminated with beryllium dusts and waste shall not exceed a removable contamination level of 3 micrograms per cubic meter.

This section of the proposed rule is not based on potential airborne exposures from surface contamination. DOE says it will only be used to provide an indication of the effectiveness of housekeeping efforts.

We believe that in a rule intended to be performance based, this proposed contamination level is much too prescriptive. As stated in the preamble, this level was selected based on existing contamination limits used within the Complex.

There are two major issues with the approach. Number one, the sites normally have more than one surface contamination limit depending on where the swipe is taken at the point of operation of a piece of beryllium machining equipment, or in an office area, as a couple of examples.

Number two, the exceedance of a swipe limit should trigger appropriate measures such as clean-up, determination of cause and corrective action, and in severe cases a stand down of operations.

Therefore we would recommend that the specific limit of three micrograms per cubic centimeter be removed from the proposed rule and that it be restated to require cleanup to a practicable level, and I think that is kind of -- that is what in the lead standard for OSHA, is that type of language, or to have each site specify surface contamination action levels in their CBDPP.

And I think many sites already have those levels in place.

Number three, the percent exceedance

approach to defining an acceptable workplace raises several implications that the DOE must understand and accept before requiring this approach.

These statistics will always show that some workers are probably exposed to beryllium levels above the PEL. Because of the inherent variability of workplace concentrations, statistically demonstrating that all exposures are below a certain number is usually impossible.

However, demonstrating successfully that no more than a given percentage of exposures are greater than a standard is possible.

This approach is contrary to the requirements defined by OSHA in most of their industrial hygiene standards. The regulatory standards are written so that no exposure above the PEL is allowed.

That is not to say the OSHA standards are right and DOE is Wrong. What it does mean is that a percent exceedance approach is a method to which the industrial hygiene and regulatory communities are not accustomed.

Finally, the percent exceedance statistical method should not be used in isolation to define an acceptable workplace. This is only a tool that must be used in combination with other objective evidence, such as, engineering controls, worker protection programs, and personal protective equipment to define an acceptable workplace.

Item four. It has also been asked whether mean testing of the data should be included. It is our position that until the dose-response is better understood, statistical analysis of beryllium exposure data should focus on understanding the entire exposure distribution, not just the upper portion of the distribution.

At this point we do not know whether a few high exposures or the average exposure concentration increases the risk for developing beryllium disease.

It is therefore prudent to fully characterize the exposure profile by calculating descriptive statistics, including the mean,tests for distribution fit, upper percentiles, tolerance limits, and exceedance fractions.

I would to now move to the medical issues.

Item one. The definition of beryllium workers excludes by design many employees who may have been exposed to beryllium. Among the excluded groups are former workers, current workers no longer working with beryllium and those with exposures below the action level.

Some of these workers are to be covered later by directly funded DOE programs. Our position is that directly funded programs be in place at the time these regulations go into effect and include a graded approach.

It is not conducive to good employee relations, nor is it fair, to have programs available to some employees but not others. In fact, some of these individuals may actually be at a higher risk for development of disease or sensitivity based on exposure levels and latency period elapsed since exposures occurred.

With regard to current beryllium workers, it is possible that there would be no medical surveillance program for some workers at UC

Laboratories who are currently engaged in work with beryllium because of the low exposure levels that have been measured.

It is the position of UC that any current worker with actual beryllium exposure be included in the medical surveillance program, rather than setting a requirement based upon exceedance of the action level.

Item two. UC supports the medical removal policy to provide protection to employees who may have become sensitized to beryllium. In fact, UC has Interim Guidelines in place that provide for this at the DOE Laboratories it manages.

We question, however, the wisdom and practicality of requiring the same program for accepted applicants. There is little justification for requiring guaranteed placement or vocational retraining for someone who has never before worked at the contractor's site.

Those applicants, who wish to do so, would be welcome to apply for other positions. Also, as a practical matter, it could take several months to

obtain conclusive test results if preliminary Be-LPT results are conflicting.

As far as we know, there is no precedent anywhere for treating accepted applicants exactly like long term employees for purposes of alternate placement.

Number three, sections 850.38 and 850.39 address recordkeeping , use of information and establishment of a DOE registry.

It is our view that these sections will provide serious will provide a serious disincentive for workers deciding whether or not to be LPT tested.

First, although maintenance of medical information as part of a worker's site medical records is probably adequate to protect privacy, for the locations with a research protocol in place, there should be no separate requirement that this information be maintained in a duplicate form in a site medical file.

That should be left to the discretion of the contractor's medical and industrial hygiene staff.

Second, the establishment of the DOE registry

requiring contractors to disclose to DOE the names, social security numbers, date of birth, gender, site, job history, and medical test results of each worker choosing to be tested is both unnecessary and unnecessarily invasive of worker privacy.

To be sure, DOE should have, and does require elsewhere in the regulation, aggregate information regarding test results without individual identifiers, but the registry has no stated purpose and it will surely convince workers to forego the tests altogether.

The confidentiality promised in Section 850.39 would provide little comfort to workers under a circumstance like this involving such deeply personal information.

Item four, while the proposal for anonymous testing could result in greater employee participation, it is suggested that the Medical Removal Protection provision in this rule would be adequate to improve the situation.

Number five, we would propose that DOE should pay much more attention to standardizing the

different laboratory and diagnostic protocols because there continues to be significant variability or results between laboratories.

It is suggested that DOE add a section to the proposed rule on standardized protocols and accredited laboratories for the performance of beryllium and LPT testing.

The administrative issues are as follows: In the preamble to the rule, it is stated that "DOE contractors are already required under DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, to have general worker protection programs."

On behalf of the UC Laboratories, I would like to point out that only specific portions of DOE 440.1A, considered to be necessary and sufficient were actually adopted into the contractual requirements for UC during the Work Smart Standards process.

However, the Occupational Safety and Health regulations, portions of the statute, and the ACGIH booklet are specifically referenced in the UC contract.

This assumption becomes especially problematic as one reads further in the preamble where it is stated that: "As specified in DOE Order 440.1A and its predecessor orders, DOE contractors must comply with both the OSHA standards and the ACGIH TLV's. "These Orders further clarify that where a conflict exists between OSHA and ACGIH exposure limits, the more protective standard shall apply."

In view of the ACGIH Notice of Intended Change to reduce the TLV for beryllium to .2 micrograms per cubic centimeter, is it the intention of DOE to require that level as its standard?

We would recommend that DOE not adopt this approach without an official change to this rule. This is necessary because economic and technological impacts, which would occur with a reduction of the standard by 90%, must be considered.

Finally, there continue to be some sections of the standard that are more prescriptive than necessary. Some examples include frequency of Be-LPT testing and medical exams.

Allowance should be made for a graded

approach based on the opinion of the physician.

Second, requirement that the informed consent form be approved by EH-1. It would be simpler to provide the elements of what should be contained in the memo and let the sites tailor their approach.

These are only examples and additional information will be included in our written comments.

In closing, we applaud the DOE for developing a proposed rule that addresses that major issues relative to Be worker protection and that is very workable.

We look forward to providing more extensive comments in writing and to working with the DOE in implementing the final rule when it is issued.

Thank you.

PRESIDING OFFICIAL MICHAELS: Thank you very much. Are there any questions or clarifications from the panel?

(No response.)

PRESIDING OFFICIAL MICHAELS: Thank you, again.

Our next speaker is Mark Kolanz.

MR. KOLANZ: Good morning. My name is Marc Kolanz. I am Director of Environmental Health and Safety for Brush Wellman Incorporated.

Brush has produced beryllium metal for over sixty years. Today Brush is the sole fully integrated producer of beryllium outside of the Peoples Republic of China and the Republic of Kazakstan.

Beryllium produced by Brush is used by the Department of Energy and others due to its unique properties and high reliability.

Strategic materials made from beryllium were used to win the Gulf War and helped to win the Cold War. Today products made from beryllium help save lives through its critical use in numerous applications including, weather satellites, aircraft guidance and landing gears, automotive safety equipment and medical electronics.

As an example, mammogram as performed with today's extraordinary diagnostic equipment, could not be done without beryllium x-ray windows.

Brush employees are justifiably proud of

the work that they do to provide these products.

We are also committed to the ultimate goal of eliminating chronic beryllium disease from the work place by controlling worker exposures.

Brush appreciates the opportunity to offer constructive comments to the Department of Energy. This is an important subject to Brush and is a subject on which we have considerable experience to offer.

Brush has over fifty years of continuous, day-to-day experience in working to control occupational exposure to beryllium. Throughout this time, Brush has also been involved in efforts to improve the prevention, diagnosis and treatment of chronic beryllium disease.

Our long history of involvement in these areas has taught us that progress occurs most rapidly when the beryllium industry and government work together. We bring that spirit of cooperation to this proceeding.

To assist the Department of Energy in its rulemaking development, Brush will submit written responses to the questions that the Department has

raised for comment, as well as information on related subjects which we believe to be important.

First and foremost, Brush Wellman wishes to commend the Department of Energy on proposing a performance based rule that starts with the end in mind, protecting the worker. The proposed rule proactively responds to uncertainties in the current scientific data in a manner based on good work practices, improved communications, and the establishment of performance expectations.

The decision to concentrate on the basics, such as worker training, work practice improvements, and measures of these improvements should result in consistent exposure reductions for the workers, both in total exposure and in the variation in exposure.

Important research is underway which may provide a scientific basis for a revision to the occupational standard for beryllium.

We agree with DOE that the existing literature does not point to a clear set of measures by which a new occupational standard could be set.

Brush has been supporting research to test

the hypothesis originally posed by Dr. Kay Kreiss, who is Branch Chief of Epidemiology Investigations within the Division of Respirable Disease Studies of the National Institute for Occupational Safety and Health.

Dr. Kreiss posed the hypothesis that further characterization of exposure parameters, such as chemical form and particle size, may play an important role in defining the potency of beryllium.

Merril Eisenbud was one of the two persons who recommended the original occupational exposure standard for beryllium back in 1949. In his 1998 paper reviewing the occupational standard for beryllium he too recommended studies be conducted on aspects of exposure such as particle size to aid in the understanding of CBD.

To that end, Brush Wellman and others are working to find answers. Brush has sponsored two research studies on particle size, particle number, and particle surface area as they relate to the potential risk of CBD in relation to process specific risks and material specific risks.

We are sponsoring these studies because

other studies have found, for example, that workers machining beryllium oxide have experienced a higher risk of contracting CBD.

Another study found lower risk in manufacturing processes involving copper beryllium alloys which contain less than two percent beryllium.

We are working to identify what is different about the materials being processed, or operations being conducted, which can cause an increased risk to the workers. These studies may suggest that what to measure and how we measure it may need to be changed.

At the request of Brush Wellman, the National Institute for Occupational Safety and Health has agreed through a signed Memorandum of Understanding to partner with us in our continuing health studies at our Elmore, Ohio and Tucson, Arizona plants.

This major undertaking allows for the coordination of resources between our two organizations which should result in a better understanding of how particle number, particle

chemistry and shape, and chemical and metallurgical form may help define a better measure of potency.

Specifically, we want to better understand the reasons for the varying potency of beryllium oxide, beryllium metal, and the alloys containing less than 2 percent beryllium.

As part of the cooperative effort with NIOSH we are also pursuing information on how often, when, why and how sensitization converts to a process which damages the lungs. We are also working to determine how continued exposure affects the process leading from sensitization to lung damage.

Likewise, DOE through its proposed rulemaking, is committed to continue its support of research into the cause and cure of CBD. Brush Wellman commends the DOE for its financial support of worthwhile studies on beryllium and recommends they dedicate funds for well defined prospective studies designed to answer specific health questions.

Preventing Chronic Beryllium Disease requires both understanding and commitment. The DOE has demonstrated both through its proposed rulemaking.

Like DOE, it is Brush Wellman's goal to eliminate Chronic Beryllium Disease.

Thank you.

PRESIDING OFFICIAL MICHAELS: Thank you very much. Any questions or clarification?

(No response.)

PRESIDING OFFICIAL MICHAELS: Our next speaker is Rafael Ponce.

MR. PONCE: Assistant Secretary Michaels, and members of the Hearing board, thank you for the opportunity to testify. I'm Rafael Ponce, a research scientist at the University of Washington, department of environmental health, and technical director of Health Hazard Identification Task Group of the Consortium for Risk Evaluation with Stakeholder Participation, CRESP.

CRESP is supported through a cooperative agreement with the U.S. Department of Energy to provide an independent academically-based perspective on their efforts to clean up former weapons production and storage facilities.

However, this support does not constitute

DOE endorsement of the views expressed by CRESP.

I would like to begin my comments by acknowledging the efforts taken by DOE to address risks to workers who inhaled beryllium, and to applaud their efforts in increased protection for workers.

These efforts by DOE have provided important opportunities to examine the health and safety concerns that arise from the industrial use of beryllium, and for these efforts the DOE should be commended.

CRESP is collaborating with the National Jewish Medical and Research Center in Denver, Colorado, to refine and standardize currently used beryllium lymphocyte proliferation test, LPT, conducting the epidemiologic research to evaluate the prevalence of beryllium sensitization among former Hanford workers.

Developing and applying molecular genetic techniques to establish genetic susceptibility markers that may underlie individual sensitivity to inhaled beryllium, and evaluating alternative approaches to the application of such genetic tools in the workplace

that conforms to ethical, legal, and social norms.

As a result of these efforts, CRESP has made several presentations on beryllium at national meetings, including the Society of Toxicology annual meeting, the Society for Risk Analysis Annual meeting, SPECTRUM.

CRESP has also presented study findings for the regional health of the Hanford site and American Nuclear Society meetings to inform both the scientific audience, and the community around Hanford regarding our research.

Copies of some of our efforts in this area will be submitted as part of our testimony today.

I'm pleased to provide comments to you on the proposed beryllium rulemaking made by colleagues and focus on several key topics that have broad implications for the proposed rule. We will submit more extensive comments by the end of the comment period in March.

Regarding the permissible exposure level, and exposure limit, a review of the existing medical literature suggests that neither the proposed short-

term exposure level, that is STEL, nor the eight hour time-weighted average, TWA, permissible exposure limit, PEL, for airborne beryllium of two micrograms per cubic meter will protect sensitive workers.

Indeed, the OSHA TLV of two micrograms per cubic meter was first established in 1949. Based on then accepted exposure limits for other metals, when there was very limited information available of the chronic effect of exposure, and without consideration of beryllium's toxicologic mechanisms of action.

Despite more recent studies that suggest that this level may not be protective, this level has been retained for more than half a century. Two such studies, which we cite in our testimony, are noted by ACGIH in their TLV documentation guide.

These studies report cases CBC In persons whose daily average exposure appear to be below the current TLV-TWA of two micrograms per cubic meter.

Additional beryllium has been suspected as a carcinogen since 1973, and in 1966 after much discussion and debate, beryllium was designated as a confirmed carcinogen, and designated A1 by IARC. No

threshold dose was proposed in this designation.

There is scientific consensus that beryllium sensitization and CBD involve an immune response, and there is strong scientific evidence to suggest a genetic basis for individual susceptibility to this disease.

Because an immune response appears to unerely pulmonary disease from inhaled beryllium, this disease is unlike other toxicant-induced environmental diseases, wherein an increase in exposure causes a proportional increase in response, and for which one may expect to establish a threshold below which on disease is expected to occur.

To minimize worker exposure to beryllium, the DOE has propose an ALARA, as low as reasonably achievable industrial hygiene approach.

Although considerable ambiguity is involved in determining reasonably achievable, this approach represents a commitment to keep exposure levels below this of an established standard through a range of preventive practices.

Under ordinary circumstances ALARA is a

recognized strategy that regards established standards of ceilings and then strives to reduce exposures still further.

However, because CBD involves an immune response, because disease occurred at levels below the proposed PEL, and because there is no evidence for an exposure threshold, DOE should be prepared for the real possibility that the only effective remedy for susceptible workers may prove to be the removal from the source of exposure.

Moreover, even within the context of an ALARA approach, the success of the strategy depends on the standard that serves as a ceiling. But with beryllium, DOE already recognizes that current standards for occupational exposure cannot be considered protective of health, and we cite proposed rulemaking 66941.

DOE's ALARA strategy should improve worker protection by setting the ceiling lower. Available controls are capable of achieving airborne beryllium levels at a fraction of the existing standard, and disease has been found below the standard.

For example, an epidemiologic study by Yoshida et al. in 1997, which we cite, suggests beryllium sensitization occurs at airborne concentrations down to 0.01 micrograms per cubic meter.

Moreover, current engineering controls and detection methods are capable of achieving airborne concentrations of 0.2 micrograms per cubic meter.

In light of this evidence we urge DOE to consider an acceptable interim PEL of 0.2 micrograms per cubic meter, until technological improvements can support a lower practicable achievable level, or until further scientific evidence is obtained to suggest that the PEL can be less conservative.

Regarding medical surveillance, proposed Section 850.33, medical surveillance is proposed for individuals at or above the action level, or above the STEL.

However, there is suggestive evidence that certain individuals may be sensitized following incidental exposures, and no scientifically defensible consensus exists regarding the definition of an

adequately protective STEL and PEL.

To minimize the fraction of workers missed by the surveillance program, that is who might become sensitized at levels below the action level, we encourage DOE to offer surveillance to all workers whose job requires work with beryllium, or for whom beryllium presents a hazard under proposed section 850.20 and 850.21.

This design would be more likely to capture the most sensitive individuals and would not rely on exposure monitoring to list a worker on the beryllium surveillance program.

Such a surveillance program would capture individuals who are sensitized at levels below the allowable PEL or STEL, and when probable location of exposure can be assigned to the worker, these sentinel cases can be used to focus more intensive personal exposure monitoring.

When coupled with LPT based medical monitoring and mapping of sentinel cases to location this approach can inform the public health model of disease prevention by defining the population at risk,

establishing efficacy of the action level, and STEL, and improving understanding of the factors that contribute to sensitization and disease.

As with the currently proposed program, this approach would also act as an incentive for employees to minimize the number of individuals who work with beryllium.

With regards to section 850.34 and 35, medical removal protection benefits, DOE recognizes that some workers may elect not to participate in the medical surveillance program, due to a concern that a diagnosis indicating CBC or sensitization could have a negative impact on future employment, or on health insurance.

A recent analysis of workplace rights reached the following conclusions. It is morally of the first importance that the worker not be confronted with the forced choice between life and health on the one hand, and economic survival on the other.

While DOE's interim Chronic Beryllium Disease prevention program seem to embrace this principle, the proposed rules represent a significant

retreat from those medical protection provisions, and stack the deck against effective medical surveillance.

The potential loss of employment after two years provides a powerful disincentive for workers to agree to the LPT test.

Why did DOE shift from their former consideration of an unrestricted policy to a policy restricting worker protection for two years? Because sensitization results in a loss of earning power, and increases the risk of future disabling illness, we encourage DOE to consider alternative options, including extending the period of job protection, formal vocational rehabilitation, or disability payments for workers who test positive for beryllium sensitization, even if no objective impairment of lung or other organ function is present.

Such options would also provide additional incentive to reduce both airborne exposure concentrations in the number of individuals who become sensitized, and demonstrate support for sensitization testing.

DOE seems ambivalent over the value of

medical removal in the event of sensitization, noting all although removal is considered prudent medical practice, no medical evidence exists to suggest that removal from exposure will alter the course of disease.

While direct medical evidence of the efficacy of medical removal may be lacking, immunologic principles indicate that continued beryllium exposure is likely to be harmful to sensitized and diseased workers.

There is ample evidence to suggest that as beryllium dose increases, the risk of disease also increases, because clearance of beryllium from the lung is extremely slow, exposures are, at least to some extent, cumulative.

Finally, the immunologic disease model shows that minimization and when possible elimination of the allergen from the receptor is required to stop the immune response.

This biology, and prudent public health practice, support the hypothesis that reduction of long term exposure is likely to reduce disease

progression.

We encourage DOE to remove sensitized individuals from continued exposure and place them in non-beryllium exposure jobs.

Regarding the use of genetic information, several epidemiologic studies support hypotheses suggesting a genetic basis for individual hypersensitivity to beryllium, and our analysis indicate that significant health protection benefits could be associated with the use of genetic screening information.

We believe that genetic information cannot be used in the workplace screening without a thorough dialogue among all parties over ethical, legal, and social implications and at the present time oppose the use of genetic susceptibility testing in pre-employment or pre-placement screening as a means to identify and prevent susceptible workers from working.

We believe efforts should rather focus on providing a safe workplace and rigorous medical surveillance.

However, we suggest that genetic

information, including HLADP-Glu-69 be made available anonymously to interested workers so they can make fully informed decisions regarding genetic testing, and future work with beryllium.

Although the positive predictive value of the Glu-69 test is somewhat low and subject to uncertainty, the negative predictive value is extremely high, approaching 100 percent, indicating the worker who tests negatively is unlikely to develop CBD at current levels of beryllium exposure.

Communication of this information would need to be performed by genetic counselors who are especially trained to understand the unique characteristics of beryllium induced lung disease, and the uncertainties inherent in the genetic test.

Taken together, the changes we propose can assist DOE in their efforts to develop an occupational health program that meet budget guidelines, technological capabilities, and public health goals.

CRESP is pleased to be able to assist DOE in these efforts, and we welcome future opportunities to work with DOE on reducing beryllium disease in its

workers.

PRESIDING OFFICIAL MICHAELS: Thank you very much. Any questions or clarification from the panel?

(No response.)

PRESIDING OFFICIAL MICHAELS: Thank you.

Our next speaker is Richard Miller.

MR. MILLER: Good morning. My name is Richard Miller, the Paper Allied Industrial Chemical and Energy Workers Union, formerly OCAW, is pleased to be able to present comments this morning.

PACE, as we are now called, has 330,000 members working in a variety of industries, and represents the majority of hourly production maintenance and environmental remediaton workers at a variety of nuclear weapon sites in the DOE complex, many of whom are either now, or were, exposed to beryllium.

PACE represents workers Hanford, Idaho National Engineering Labs, Brookhaven, Oakridge, K-25, Portsmouth, Paducah, Mound, Grand Junction, Argonne East and West, and most recently workers at the WIPP

elected to join our union.

First I would like to address the scope of the rule. We believe that these rule should be expanded to cover the needs of both current and former workers.

We note that former workers are specifically excluded in the definition sections, and in the coverage of this rule. Most notably DOE has failed to include a compensation program to address the pressing needs for health care and income replacement, and to take steps to offset the stigmatization associated with having a positive CBD test.

The rule, in our view, should not go forward without addressing the socioeconomic and health care needs of sensitized and ill workers.

Moreover, we believe that suppliers of beryllium to DOE should be required to comply with the substantive provisions of a final rule.

Within the category of former workers, which I will address first, in our union we have had a number of members exposed to beryllium at K-25,

through the S-50 complex, which was run in the '40s and '50s, and those who were involved in the later '50s in the DND evac.

Likewise we have also identified reports showing grossly contaminated ventilation systems in the S-50 support buildings, and classified those buildings as unsuitable for storage.

A second source of beryllium at K-25 was in the K-1401 building, which is where machining of beryllium parts for Y-12 was undertaken, reportedly for the late '60s and early 1970s.

This information was also provided under the Former Worker Medical Surveillance Grant report for needs assessment.

In addition, at the INEEL, there has been extensive exposure to beryllium and you will see, in our testimony, at various reactors it was used largely as a neutron deflecting material, including the MTR, the ETR, the advanced test reactor, which is still running, the EVR-2, which is now in the decommissioning phase, ZPPR, the ANP and the EBOR.

Moreover, we note that a CDC report

spotted 45,455 pounds of beryllium in inventory at the INEL, which indicates that it is still substantially on hand at that time.

Beryllium machining was commonly done at this facility, particularly at the TAN facility, ATR, ETR, MTR, WRRTF, and the test reactor areas. And particularly what was interesting was that there were chop saws used to actually cut the blocks of beryllium, and there was no evidence that protective equipment was provided for its use.

In addition, industrial hygiene data we have uncovered shows that beryllium was used for thermocouple fabrication, and these include trimming, welding, splicing, bracing, and soldering, and covered machinists, mechanics, pipefitters, reactor operators, equipment operators, and process operators.

So we have a clearly at-risk population at the INEL, as we do as well at Mound. In addition the University of Washington, under its DOE medical surveillance program has spotted at least 682 workers who worked in beryllium buildings, and were exposed based on their job exposure classifications.

We would also like to, while on the subject of former workers, would like to draw your attention to employees of beryllium manufacturers who supplied material to DOE. This particularly applies at facilities such as Hazelton, the former Kawicki Berylco facility, as well as the Reading facility.

This was used as Cold War material by the DOE and the AEC's as predecessor. The Hazelton facility processed beryl ore from 1957 to 1981 under an AEC direction, and supplied that process material to Rocky Flats.

This particular Cold War legacy includes excess mortality amongst beryllium workers, and historical reports indicate frequent levels of beryllium well above the OSHA standard, often ten to fifty times the allowable limit, and selected area samples at the Hazelton plant indicated up to 1,000 micrograms per cubic meter.

This plant, which employed more than 1,200 people during its history exceeded regulatory levels in at least the 15 reports provided to the Manhattan office, to the AEC, according to the Times Ledger of

Wilkes-Barre, the newspaper article.

The AEC itself closed the Kawicki Berylco facility in the late 1950s, due to poor health and safety conditions, a remarkable achievement in that period.

The facility was shut down without appropriate resources to combat the consequences of beryllium exposure amongst these workers.

At this point, and in response to this evidence of beryllium disease, the DOE's Deputy Assistant Secretary for Health, Dr. Seligman, who we are pleased to see here today, authorized a medical surveillance program, which is being headed up through Michigan State University in cooperation with the University of Pennsylvania, the University of Cincinnati, and Emory.

We, to date, just to summarize, there are 664 individuals who had both x-rays reviewed and lymphocyte transformation tests completed; 103 of these individuals were referred for further testing, and some of them, 37 had a positive blood test, 56 because of abnormal X-rays, 8 because of both, and

then further testing was evaluated for 23 of them at the University of Pennsylvania.

Almost half, ten, have chronic beryllium disease. Of those who elected to have follow-on testing. In other words, you did an initial level of screening, then what happened was people were spotted with either a high X-ray, and abnormal X-ray or high LTT tests, at that point they were subjected -- or offered the opportunity, rather, for further testing, only 23 of the 103 referred for further testing participated, and of those nearly half had chronic beryllium disease.

We also believe that participation in the screening programs, which as the data we will submit to the Department indicates, is uneven, where there were organizers on the ground in Hazelton, we had high participating rates, in Reading, where there were fewer organizers we had a lower participation rate in the screening program.

We believe if there was medical care and compensation for these workers, and an advocacy office set up to help participation by these workers, one

might find a higher involvement in what appears to be necessary screening.

We believe that the rulemaking, therefore, needs to be expanded to cover the needs of former workers some of whom, I might add, will be laid off from DOE in the foreseeable future, or have already been laid off as DOE moves to close its various weapons production sites.

And, secondly, the rule needs to be expanded to cover those Cold War veterans who worked for suppliers under contracts through the AEC and DO.

These two groups should not be allowed to fall through the cracks, as DOE seeks to remedy the harms it has imposed on its workforce as part of its cold war mission.

As noted earlier, we believe this rule should be modified to reflect the fact that beryllium is a confirmed human carcinogen, something that is not noted in the rule.

And we know of no safe level of exposure to this particular carcinogen. As noted earlier, beryllium is a confirmed human carcinogen according to

IARC, and it has been designated as a 1.

In our view, where there is no detectable level for a carcinogen, any exposure at all may be deadly, and therefore we would recommend that the DOE modify its rule accordingly.

The first choice we would offer is a no detectable level. If this is not feasible, then we would recommend an 8 hour threshold limit value of .05 micrograms per cubic meter, based on health effects.

As noted earlier, ACGIH recently recommended 8.2 micrograms per cubic meter, time weighted average exposure. And, of course, this is ten-fold lower than what is proposed in the rule.

The proposal that we have made today, at .05 micrograms per cubic meter, which was developed in consultation with people at OSHA, is simply a four-fold protective factor over the ACGIH, what we believe consensus recommendation.

This recommendation was published in November and December of 1998, at about the same time your rule came out, and was approved by the Board of Directors of ACGIH in October of 1998.

We also want to draw your attention, within your own preamble, to the fact that chronic beryllium disease have occurred in machinists at the Y-12 beryllium ceramic machine shop, where levels have been quite low.

In fact, 90 percent of the samples taken were below the detection limit at the time these samples were done, which is in the '80 to 1990 time frame, and yet there were still incidents of CBD reported in that population.

So DOE now has, at least for that group of workers, some substantial evidence upon which we believe it should rely in lowering the standard.

We also want to draw your attention to the need for some diversity in selecting medical advice. The medical surveillance section in the proposed rule provides the contractor with virtually unlimited power to administer the program, and in our view puts the contractor in a position of the fox guarding the chicken coop.

We propose an alternative plan using the OSHA lead standard as a model, and in the lead

standard there is a provision for multiple physician review mechanism, where the employee is entitled to a designated second physician when the employer selects the initial physician to conduct the medical exam.

If these two physicians are unable to resolve a difference, the employee is then entitled to bring in a third physician.

We also want to draw very strong attention, as did, we note, the Steel Worker's Union in its advertisements that ran in both the Denver area paper, and in the Washington Times this week, to what are seen as an unlawful, if not unethical medical removal provision, and allow us to detail our concerns.

The proposed medical removal plan at part 850.34 provides beryllium workers with two or more positive Be-LPTs, or confirmed CBD with the following options with respect to continued employment or income.

A, contractors are asked to make reasonable efforts to find alternate employment, provided you don't displace anybody else, and if there

is retraining required for that new job, you can't exceed 6,000 dollars in training, and I don't know whether that includes salaries or not, and no one is required to be promoted under the rule.

So if you don't have a job for someone, then we need to examine what the consequences are.

Secondly, the rule provides that where employment can be found workers are assured of what is known as rate retention, retaining their previous levels of pay and benefits for only two years after medical removal.

So if they are moved to a job for which there is a lower pay classification, rate retention evaporates after two years.

We believe this is not only inequitable, but the burden shifts back to DOE, because it is DOE who poisoned these workers to begin with, they ought to at least have the decency not to make sure that workers should be asked to pay twice, once with their health, and secondly with a lower paycheck.

For those who cannot find employment, or where replacement employment cannot be found in a non-

exposed environment under the medical removal provision, the key question then is, what will happen to those workers?

First, these workers can be laid off. And workers are left to fend for themselves. Secondly, for those facing loss of employment DOE rule allows affected workers the choice to return to work at a beryllium contaminated area if they sign an informed consent waiver.

A waiver we note, by the way, that was not published in the rule, so we don't know what is being waived, and we would appreciate if you would make public precisely what it is people are waiving. Are they waiving liability claims against the department, what is it specifically that they are waiving?

Moreover, to force people into the choice between choosing between their incomes and their health or lives, is not only barbaric, but it creates a potential legal conflict for the department.

What is the legal conflict? DOE orders require contractors to comply with OSHA standards, and compliance with these is what is also embodied in

DOE's contractual provisions.

One of OSHA's most basic rules is that an employer must provide a workplace free from recognized hazards. However, the proposed rule carves out a loophole which says that an employee may waive this OSHA requirement if the employee signs a waiver of the medical removal provision.

OSHA law creates no exception to the requirement to maintain a workplace free from recognized hazards. Nowhere can we find in the OSHA act where workers can waive these.

And the proposed rule would authorize an inherent conflict between the employer's obligation to maintain this workplace free from recognized hazards, and the contractor's freedom to present workers with a choice to waive this obligation.

And this would not be very difficult because they are then confronted with job blackmail. The coercion is so evident, it is so plain, it so jumps out off the page in this rule, that I really urge you to re-examine the moral and ethical basis of this particular rulemaking.

Indeed, we would like to know, precisely, whether this is the view of the Secretary of Energy, whether this is the view of this particular administration, that workers should be forced to make that choice.

And if it is, we would like you to declare it clearly and upfront, so that everybody can examine, explicitly what is implied in this rule.

We also believe that DOE's position is inhumane. After poisoning its workforce DOE now says workers are going to lose their job to a medically justified removal protection can keep their job if they agree to further endanger themselves.

Again, as we note above, this is raw coercion, and moreover will deter workers from participating in any beryllium LPT test. If you are going to vote to stigmatize yourself, and vote to stigmatize your income, you are unlikely to participate in this particular program.

We have an alternative we would like to suggest that you consider. First, where work with the contractor is not available, and a worker is laid off

due to medical removal, the worker would receive 100 percent income replacement, adjusted for inflation, and equivalent health insurance to those offered by their employer until they reach retirement age.

Two, where work is available there shall be no loss of income, benefits or seniority for as long as they remain employed, instead of the regimen that limits rate retention to only two years.

In addition DOE needs to, in complimenting this particular approach, address the needs of beryllium workers who were subsequently laid off for reasons of other than medical removal or already former workers.

These workers face a stigma in labor markets simply as a result of DOE employment, and to the extent that they have CBD, they could be further stigmatized.

For these workers we recommend the following; that DOE provide a supplemental health insurance policy at no cost to all sensitized, exposed, or CBD workers, or those who contract cancer, to cover 100 percent of diagnoses, medical

surveillance treatment, and all related health care costs associated with beryllium exposure, including resulting complications, and extraordinary measures, such as lung transplants.

And secondly to deal with income replacement, DOE shall arrange for workers to obtain coverage under FECA or the Longshore and Harbor Workers Act, and establish a clear cut presumption of work relatedness and causation for any beryllium exposed worker employed by DOE, or its contractors, or suppliers, and secondly, to require contractors and suppliers to participate in this program as a condition of receiving or retaining a DOE contract.

We also believe that DOE should utilize NIOSH in concert with its contractors and unions, where appropriate, to notify affected workers of this change in benefit availability. And NIOSH has an excellent notification program for at-risk workers.

We will offer you further comments in this area, but we want to just flag for you that there has to be a socioeconomic framework to deal with this. You cannot deal with a medical removal provision, and you

cannot deal with the consequences who are laid off, in a vacuum from the rest of your rule.

On the question of enforcement, the particular rule under Part 850.5 says, go to the grievance and arbitration of a collective bargaining agreement.

Allow me to point out some concerns. The proposed rule erroneously assumes that an arbitrator, in a labor dispute, would find that the final rule that DOE promulgated would be part of a collective bargaining agreement.

In point of fact, unless DOE required employers to propose this rule as part of a collective bargaining agreement, and unions willingly accepted it as a contract condition, an arbitrator would decline to enforce this rule.

So you have proposed an enforcement mechanism which will not work, it ain't gonna happen. No arbitrator will enforce outside of the four corners of a collective bargaining agreement. That is black letter law.

Secondly, while an employer must, and we

agree with this provision of the rule, bargain over a change in the terms and conditions of employment, as required under the National Labor Relations Act, DOE has not determined that costs will be considered allowable if a contractor decides to bargain for a level of health protection, or other terms and conditions which exceed the minimum requirements of this rule.

So if it is not an allowable cost, it probably ain't gonna happen.

DOE should also be clear about whether the terms of this rule are subject to negotiation between a union and a contractor, if you want to put it in the ambit of a collective bargaining agreement.

And yet, on the other hand, the preamble to the proposed rule suggests that DOE did not even intend that the rule be subject to labor management bargaining because of the concern of uneven application and an uneven quality of the rule.

So in one hand of the preamble you are saying, we don't intend that this be subject to negotiation, and the next breath you say it is

enforceable through a collective bargaining agreement. You can't have it both ways.

Moreover, given the deficiencies of this rule, I know of no union that would ever propose this rule, certainly not our union, as published in the Federal Register for inclusion in any collective bargaining agreement.

We recommend that DOE make compliance with this rule an extension and a part of the Price Anderson enforcement program. Under 10CFR Part 820, or include it as part of the enforcement regimen which was required under Section 3131 of the FY92 Defense Authorization Act, a draft rule, I believe, that was promulgated for, or was going to be promulgated under the HAZWOPER program, but for some reasons never moved forward.

We also take exception to the enforcement of this rule under 850.4, because it is simply limited to DOE, which means probably the contracting officer, taking "appropriate steps" with respect to contract enforcement.

First, if a contractor is in breach of

this rule, the notion that you are going to terminate a contractor is almost heresy. And for you to say so in the rule seems absurd. Do we know of any prime contractor that has ever been terminated for violating a health and safety rule in the DOE complex? Has any ever been fired? Of course not.

So why put it in a rule, it creates a false expectation, and it creates an illusion that there is going to be a consequence, when in fact there won't be.

Secondly, award fee reductions are useful only to the extent that a contracting officer finds out about non-compliance. So to the extent that the contracting officer is qualified, or has qualified people to go out and determine this compliance, perhaps they could then adjust an award fee, if it was put in an award fee plan in advance.

The better way is to give workers a fully staffed Price Anderson enforcement office where they can call upon to bring alleged violations, have experts come out and investigate the matter, and while awaiting a compliance officer, we recommend that

workers should have the right to shut down the job without loss of pay.

Finally, to the extent that workers are represented, DOE should make clear that an employer representative may file grievances under the union's collective bargaining agreement or seek other remedies under the National Labor Relations Act to compel contractor compliance, or deter retaliation for seeking enforcement. And I think particularly of section 502 of the National Labor Relations Act, or unfair labor practice charges.

However, the core enforcement responsibility should not rest with the workers, it should rest with the people who own these facilities, and that is the energy department, and you all ought to go out there and police -- you ought to be in a position to police what is going on out there.

And if you are waiting for people to volunteer violations, and submit them willingly, you are not going to get very much self reporting of non-compliance.

Finally, this rule is not a consensus

product of the Beryllium Rule Advisory Committee in which we participated, and we think it should be made clear in the preamble.

We will submit detailed comments on a line by line item. I appreciate your forbearance with this long testimony, and your attentiveness. And if you have any questions, I would be pleased to answer them.

PRESIDING OFFICIAL MICHAELS: Thank you very much. Any questions or clarifications from the panel?

(No response.)

PRESIDING OFFICIAL MICHAELS: Are there additional speakers that would like to speak? Please come forward and identify yourself.

MR. KOLANZ: I'm Mark Kolanz, I represent Brush Wellman, Incorporated.

I wish to add some clarification to some of the comments of Rafael Ponce and Richard Miller. And I first off kind of invite DOE to carefully evaluate for themselves the research quoted first by Rafael Ponce, and his justification to suggest a 0.2 microgram per cubic meter standard.

He referenced a couple of items, first the ACGIH, and the two main documents that they utilized in coming up with their suggestion. Those two studies were the Coat Study and the Collen Study.

I should point out that the Coat Study was general area sampling, just as has been experienced in the DOE facility. And if you look carefully at that study, I don't remember all the little points right off the top of my head, but in that study, if you look at it, the highest levels that they recorded were in the locker room, which gives you an idea of how contaminated these folks were, if that is where they were measuring general area samples as the highest.

In the Collen study, which is a study of precious metals refiners, the researchers tended to ignore the fact that roughly about 11 or 12 percent of those samples taken over two two week periods were offer the two microgram standard.

We -- there were also levels recorded there as high as 40 micrograms per cubic meter. Again, this was kind of ignored in the title of the document.

There was also reference made to a Yoshida study, which was printed last year, that pointed to exposures below two micrograms, causing both sensitization and disease.

The important part of that, again, was general area samples only. In Japan, their law requires them to sample for general area, and that was clarified in a letter to the editor, and a response to that letter to the editor by Mr. Yoshida in a recent edition of the same publication.

I want to point out that the occupational standard isn't a mean or a median, it is a standard we are not supposed to be exceeding. And repeatedly people have been exceeding the standard.

It is important that we can't make judgements of a standard if people aren't complying with that standard. It is a limit, not a mean or median, and it needs to be viewed and looked at in that fashion.

With regard to a couple of the comments made by Mr. Miller, he did reference that maybe there is no safe exposure limit for beryllium. I would

suggest that he may want to take a shovelful of soil from his backyard and have it analyzed. Soil across the United States contains one to two parts per million beryllium. In a typical shovelful of soil, assuming it weighs a kilogram, that would be a thousand micrograms of beryllium in a shovelful of soil almost anywhere in the country.

So I think that is a fairly arbitrary and non-scientific way to approach this.

I have the same comments with regard to -- he is pointing towards taking the ACGIH and then arbitrarily cutting the proposal by four. Again, that is a very arbitrary approach, there is no scientific basis for it.

The current proposal by the ACGIH, based on their protocol is that number .2 is out for scientific review. And, yes, it was adopted by the Board of the ACGIH as a proposed value, and under their bylaws are required to put that out in the public sector for about a year, a minimum of a year for scientific comment and review, and it should go through that.

Lastly, Mr. Miller also made comment of the number of samples, again, below the standard. And I find that we need to pay attention to the number of samples taken that have been above the standard.

Thank you for your time.

PRESIDING OFFICIAL MICHAELS: Thank you, any further points of clarification, or unscheduled speakers?

(No response.)

PRESIDING OFFICIAL MICHAELS: In the absence of additional speakers we will adjourn until additional speakers appear, if they do I'm appointing C. Rick Jones to chair in my absence, and we will reconvene if other speakers do appear.

Thank you all for your attendance and your participation.

(Whereupon, the above-entitled matter went off the record at 10:15 a.m. and went back on the record at 11:20 a.m)

MR. JONES: This is Rick Jones, I will be the Presiding Official in the absence of Dr. Michaels.

It is now 11:20 on February the 11th. I would like to

reconvene the public hearing for the Notice of Proposed Rulemaking on the Chronic beryllium disease prevention program for DOE.

We have an additional speaker. I would like to, at this time ask Professor Ilise Feitshens to come to the podium and present her oral remarks.

Please announce your name and your affiliation, and how you are representing today.

MS. FEITSHENS: Thank you. My name is Professor Ilise Feitshens, and I work with Health International, and I'm adjunct faculty at Cornell University School of Industrial Labor Relations.

I'm also very pleased to report that I have been recently appointed as legal advisor to the World Health Organization Russian Academy of Medical Sciences Experts on Reproductive Health at work.

There are some other credentials I have that are listed in my written comments, which I will not bore you with.

But I'm here today in my capacity as a member of the Beryllium Rulemaking Advisory Committee that convened in 1977, or as we called it, the BRAC.

The BRAC was convened to grapple with some of the difficult legal, ethical, and scientific issues caused by long term exposure to beryllium in the workplace, as correctly described in 63 Federal Register 66942, Thursday December 3rd, 1998, which is the Notice of Proposed Rulemaking we are discussing today.

I won't repeat the entire description here, but that correctly characterized the BRAC as a diverse set of stakeholders, and it had experts from industry, labor, medicine, academia, and we in fact generated a set of recommendations which are extremely consistent with what is reflected in the proposed rule.

BRAC studied uncertain scientific questions, and the hard policy choices to be made in guiding an even-handed policy that promotes worker health in light of the undisputed need to one, minimize the number of workers exposed to beryllium; two, to minimize exposures; three, to establish medical surveillance; and four, assist affected workers who are dealing with beryllium health effects.

I am very pleased to say that there was a

high quality of deliberation in those discussions, as a very large percentage of the consensus that came out of those discussions is reflected in the proposed rule.

In its deliberations BRAC heard testimony from a vast variety of experts, and also from injured workers who suffer from chronic beryllium disease, and their families, who live with the fallout of their breadwinners occupational illness.

I was asked to provide a short presentation that considered ethical and legal issues raised by lymphocyte proliferation testing, as it is called, LPT, among previously exposed beryllium workers.

And there was discussion about the history and law of informed consent regarding new or uncertain medical testing, and how that bears witness to the notion that sometimes legal and ethical issues are distinct, but in this situation they are not, insofar as sensitization has occurred among those workers whose bodies adversely effected by beryllium specific lymphocyte proliferation, and testing has demonstrated

that an individual's immune response to beryllium exposure exists.

From the standpoint of occupational safety and health policies regarding past, present, and future beryllium exposure, the ethical and legal issues are inextricably linked, and for this reason the proposed rule has correctly adopted a wise path by embracing medical surveillance programs to former employees, as well as current employees, and by requiring baseline data and periodic medical evaluations.

BRAC was also persuaded that confounding variables, such as inadequate data and the effect of genetic predisposition made it difficult, if not impossible, to resole issues regarding thresholds and margins of safety for exposed beryllium workers.

We were very concerned about this, and for this reason urged that there be some very strong monitoring and surveillance protection. And each of the components in the medical surveillance program outlined in the proposed rule is necessary and appropriate, and consistent with BRAC's findings.

The proposed rule correctly reflects BRAC's concern that workers have an access to sound, ongoing medical information, and the opportunity to have counseling regarding the complex decisions about their future treatment.

This is true today when making decisions about lymphocyte proliferation testing, it may be true in the future for other complex tests that we don't yet have more certainty about, more reliability about.

And in light of individual risks, of either past, present, or future exposure, some of which may not be well understood now, it may be better understood in the future, the predictive value of tests, and the benefits to the employee having such information.

Ethical concerns about balancing cost benefits, testing, the availability and the accessibility of reliable testing, with a good predictive value, the employee or former employee exclusions or inclusions in various programs, right to know information, the rights and consequences of not knowing such information, informed consent, future

obligations to provide medical care and followup.

These can all be examined from the standpoint of past, present, and future exposures, and they were all discussed in our meetings.

The informational requirements and PTL components of the medical surveillance program in the proposed rule, therefore, reflects and constitutes a good faith effort to incorporate the best practices, into a flexible regulatory framework to provide workers with needed information, and to embrace new preventive medical technologies, as they emerge.

Specifically, the approach requiring a written medical surveillance plan, medical removal protection, and counseling regarding the appropriateness, potential consequences, benefits, and related information using LPT as just one example, is a crucial instrument to providing the beryllium exposed population choices, and relevant information to make intelligent life-saving decisions regarding the risks associated with their work, and future medical testing and treatment.

There was also a consensus among BRAC

members, that we have some moral, or ethical, or legal obligation to provide people with testing. We debated about whether this was free of charge and how to compensate for a failure to provide adequate information at the time.

We looked at a lot of questions, and thought about them very carefully, without really having hard and fast answers. BRAC examined questions such as if the LPT is positive, should there be a second opinion, should there be follow-up treatment?

Was the scope of such coverage for present employees, who pays for such medical protections? And if there is an implicit effect on the employees insurability, which was discussed by several people, meaning that medical coverage might be denied, is there a duty to inform employees of this possible consequence, is that enough for an employee who also has past exposure?

Is there some duty on the part of DOE, or a facility operator, to attempt to ensure coverage of this class of employees through negotiations with an insurer, or through legislation?

Can this class of workers have adequate protection, regardless whether they have a negative LPT.

BRAC recommended that there be some requirement for a pre-test or pro-test counseling, with some attention to establish notions of informed consent, as is reflected in the proposed rule, because of the complexity of these questions, which will change over time.

The US DOE's proposed correctly recognizes, also, consistent with BRAC's recommendations, that there is some duty to disclose information without giving names of the people who took the test, and how it impacted on their work and their lives.

For this reason the department realized that some workers may elect not to participate in medical surveillance program, and as discussed in the preamble of the proposed rule, "Because they may believe that a diagnosis of CBD could have negative impact on future employment opportunities, or their health insurance, thereby impeding participation in

even the best of well intended coverage."

Outreach programs are also an important part of this approach, and will save many lives from needless suffering by providing greater access to appropriate medical care.

In conclusion, the U.S. Department of Energy is to be commended for attempting to reduce harm, and minimize risks to workers who have potential exposure to chronic beryllium disease even if, in the case of some workers and their families this action is sadly belated.

This rule represents an important recognition of a latent salient problem of occupational health, a rule that can serve as a model to inspire other agencies to protect their employees, a rule that will also honor the hard work of people whose health may have been compromised in the patriotic endeavor of protecting our nation through the peaceful manufacture, transport, and storage of nuclear weapons.

It will save lives, and it will serve as a model for excellent health protections in other

areas of occupational health in the future.

This proposed rule, therefore, should be brought to fruition as a final regulation. Thank you for your attention, and if you have any questions I will try to answer some.

MR. JONES: Points of clarification?

(No response.)

MR. JONES: Thank you so very much for your comments, and they are very much appreciated.

Is there anyone else who at this time would like to make additional comments?

(No response.)

MR. JONES: Thank you very much. I would like the record to show that we are once again adjourning the public Hearing until such time as we do get an additional speaker.

(Whereupon, the above-entitled matter went off the record at 11:27 p.m. and went back on the record at 12:15 p.m.)

MR. JONES: This is Rick Jones, the presiding official. It is 12:15 and the Public Hearing for the Department of Energy's Notice of

Proposed Rulemaking on Chronic Beryllium disease prevention is adjourned.

(Whereupon, the above-entitled matter was concluded at 12:15 p.m.)